

Current opinion on catheter-based hemorrhage control in trauma patients

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Surgery has undergone several fundamental paradigm changes during the last 25 years. Laparoscopic and catheter-based interventions have become common, ultrasound is ubiquitous, and robotics and damage-control surgery are commonplace. When combined with ever-advancing imaging technology, all these tools will continue to change the face of trauma surgery. Accordingly, the University of Texas Health Science at Houston, the Memorial Hermann Texas Trauma Institute, and the Methodist Institute for Technology, Innovation, and Education held a 2-day meeting on February 26 to 27, 2013, to discuss

developing new techniques and potential paradigm shifts for catheter-based hemorrhage control including the trauma hybrid operating room (THOR) concept. At this meeting, 60 North American physicians from more than 25 institutions including leaders from the American College of Surgeons and representatives from six specialties (trauma, vascular surgery, orthopedic surgery, critical care, general surgery) involved in caring for traumatically injured patients met and discussed relevant clinical problems, the technology needed to improve patient care, patient-centric flow patterns, new treatments, training, credentialing, and competency issues and participated in a catheter-based hemorrhage control skills laboratory for acute care surgeons. The following is a summary of the proceedings.

DEFINING THE CLINICAL PROBLEM

In trauma patients, early deaths occur at much higher rates than late deaths. For example, from 1999 to 2008 at Memorial Hermann Hospital in Houston, 58% of trauma mortality occurred in the first 24 hours after hospital admission, 14% during Day 2, 20% between Days 3 and 6, 5% between Days 6 and 30, and 3% from Day 31 onward (Fig. 1). Most early in-hospital deaths are caused by hemorrhage, and hemorrhagic deaths among patients occur at a median of 2.6 hours after admission.¹ Mortality rates of injured patients presenting with hemodynamic instability exceed 50% in several military and civilian studies, and hemorrhage is the leading cause of death in the ongoing war.²⁻⁵ Additional research suggests that in-hospital mortality caused by chest or abdominal trauma peaks between 1 hour and 6 hours after injury.⁶ For these reasons, rapid and effective methods for the treatment of traumatic hemorrhage are needed to achieve hemostasis. Currently, the following “fast” methods are used to control bleeding: external compression on extremity and junctional injuries, surgical interventions for noncompressible torso hemorrhage (NCTH), and blood products and procoagulant medications as adjuncts to rapid surgical intervention. While angiographic embolization and aortic occlusion balloons have been routinely used for the last 20 years, in most current instances, they are slower at achieving

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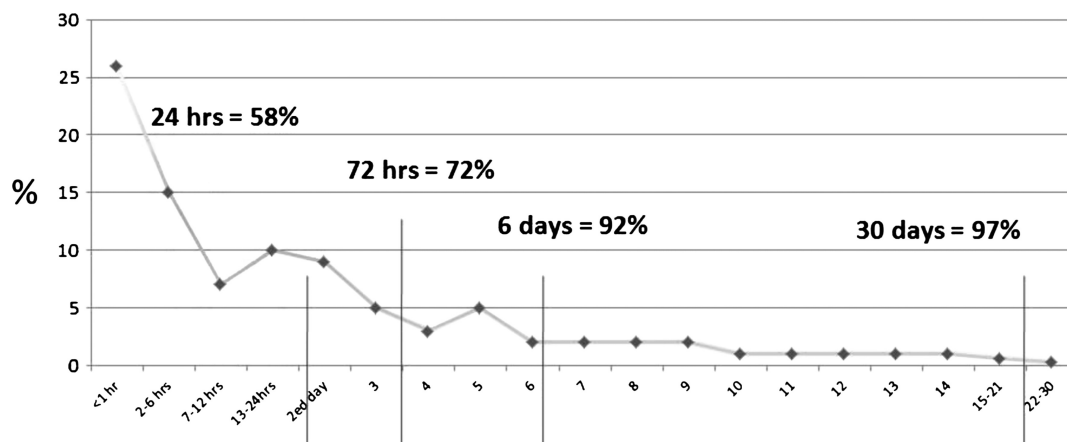
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Trauma admissions = 36,028
Overall deaths = 2394
Overall mortality = 6.6%
Deaths from day 31-171 = 68/2394 = 3%

Figure 1. Memorial Hermann Hospital trauma admission mortality, 1999–2008.

hemorrhage control than standard operative interventions for the treatment of traumatic hemorrhage.^{7,8}

TREATMENT DELAYS IN HEMORRHAGING TRAUMA PATIENTS

Treatment delays in hemorrhaging trauma patients are a serious problem because of the high risk of death caused by hemorrhage in the first initial hours after the injury. In patients with NCTH, treatment decisions are complicated by multiple factors, such as polytrauma, variable in-hospital locations for advanced diagnostic imaging, catheter-based and open surgical procedures necessitating intrahospital transport,⁹ and varying availability of specialists depending on the day and time of injury. In typical civilian Level 1 centers, trauma surgeons decide whether to transport a bleeding patient to a physically separate computed tomographic scanner, operating room (OR), or interventional radiology (IR) suite from the emergency department (ED). All three are important for a fast and accurate diagnosis of the source of traumatic hemorrhage, but the fundamental problem is that none of these three locations are ideal for all diagnostic and intervention options that may be required (Fig. 2). The OR may be the best place for open surgical procedures but usually has limited imaging and angiographic capabilities. The IR suite and computed tomography are not optimal for resuscitation or open surgical interventions. If the surgeon chooses the wrong location based on the often incomplete information gathered in the first few minutes in the ED, treatment delay is likely and risk of mortality increases.⁷ Another risk of these “locational silos” is patient transports throughout the hospital and handoffs between multiple medical teams, which may also increase patient complication rates and mortality.^{10,11} Treatment delays may also occur for patients who are injured at night or on weekends, when interventional radiologists are not typically on call in the hospital.¹² Finally, the critical anatomic

bleeding sites that exsanguinating trauma patients manifest may be physiologically dynamic, often evolving, and multiple.

POTENTIAL SOLUTIONS

One technique to decrease mortality from abdominal exsanguination may be resuscitative endovascular balloon occlusion of the aorta (REBOA). ED-based endovascular balloon occlusion of the aorta holds promise for patients with NCTH by rapidly controlling abdominal and pelvic hemorrhage and increasing central aortic pressure until definitive hemostasis can be achieved.^{13,14} Achieving aortic occlusion has traditionally required a thoracotomy or a laparotomy for aortic exposure in the ED with direct aortic compression performed to evaluate and treat reversible causes of cardiovascular collapse.^{15–17} Where resuscitative thoracotomy is used, the mortality rate,

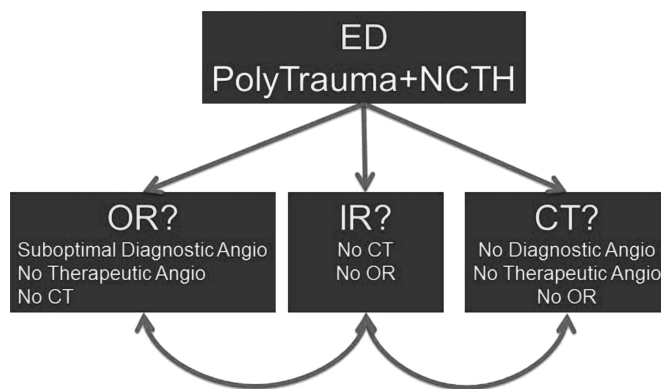


Figure 2. Trauma decision point.

morbidity, and cost of the procedure is high owing to the nature of the injuries.¹⁸ High mortality rates (88%) are also found among combat casualties who undergo ED thoracotomy.¹³ Similarly, aortic occlusion for extrathoracic injuries via thoracotomy or laparotomy carries a high mortality rate, and current management protocols are hampered by small sample sizes.^{15,19}

REBOA has not been applied broadly partly because the skills and equipment needed to perform the procedure may not be well understood by non-vascular surgeons,²⁰ although it was well described in 1954 by Hughes²¹ and in 1989 by Gupta et al.²² Brenner et al.²³ have recently described their civilian experience with six cases of REBOA, with favorable initial results. Familiarity with catheter-based procedures is increasing, and trauma surgeons are becoming more open to learning these techniques.^{24,25,26} In addition, several training courses have been developed to advance these skills in acute care surgeons. The Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) Working Group has developed and implemented a 2-day curriculum based on didactic instruction, endovascular simulators, and live tissue models. Another course, the Basic Endovascular Skills for Trauma (B.E.S.T.) has also been developed covering the use of guide wires, catheters, sheaths, and imaging technology over 1.5 days (Edwards Lifesciences, Medical Simulation Corporation). Similar courses have been developed outside the United States. Centers using REBOA are now questioning if it will replace ED thoracotomy for rapid control of nonthoracic hemorrhage. However there are some limitations to REBOA, including the fact that it requires a cut-down for access and surgical repair of the femoral artery at the completion of the procedure. New versions of this technology will obviate these limitations.

Another more comprehensive, expensive, but fundamentally paradigm-shifting solution is the use of advanced systems approaches such as hybrid ORs. The dedicated THOR, a combination of surgical and IR suite with advanced imaging capabilities, would allow all equipment required for rapid intervention and technical support to be centrally located. In addition, clinical specialists would come to the patient instead of transporting the patient to multiple different locations. This patient-centric design is likely to decrease patient movement, time to hemorrhage control intervention, simplify surgical decision making, and therefore would likely improve patient care and outcomes. With a THOR available, patients can be transported to a single location and surgeons can apply different modalities as needed. In a THOR, it is also possible to transition from minimally invasive to open surgical procedures in emergent situations without the need to transport unstable trauma patients, potentially reducing transfusion requirements, ventilator times, risk of infection, and total procedure time. Because in many trauma centers, interventional radiologists do not provide 24/7 in-hospital coverage, resulting in delays in treatment,¹² THOR may be especially beneficial in cases where IR capability is required. An approach similar to THOR, called *RAPTOR* (resuscitation with angiography, percutaneous techniques and operative repair) suites, have recently been installed in Calgary, Canada, and Sydney, Australia, as well as the Karolinska Institute in Sweden.²⁷ New devices and monitoring in conjunction with a THOR may facilitate the optimal delivery of care for patients with NCTH. However, published evidence on the clinical benefits of hybrid

ORs is minimal at this time, especially for patients with traumatic injuries.

COMBINATION APPROACH

There is an opportunity today to combine these complementary approaches, REBOA and THOR, as well as integrate other existing but evolving endoscopic and laparoscopic techniques. The ability to combine these minimally invasive techniques in various sequences is also promising. For example, if a patient's injury or physiology allows the time, minimally invasive techniques can be used. However if the patient's physiology deteriorates, all minimally invasive equipment can be moved aside and standard open approaches can be rapidly used, all in one location. In support of a combination approach, there are surgeons now completing a second standard vascular fellowship after their trauma/surgical critical care fellowships. This may be a natural evolution of acute care fellowships and the future of trauma care.

COMPETENCY AND CREDENTIALING IN CATHETER-BASED HEMORRHAGE CONTROL

At present, no common standard for competency/credentialing exists for endovascular interventions for catheter-based hemorrhage control, but we must work toward this goal for the future, being certain to include the trauma and acute care surgeons in the provider group.

Recommendations for attaining and maintaining the cognitive and technical skills necessary for the competent performance of catheter-based vascular peripheral interventions have been published by national cardiology and vascular surgery organizations.²⁸ Catheter-based vascular interventions are unique areas of competence, and physicians from several subspecialty backgrounds (cardiovascular medicine, vascular medicine, IR, vascular surgery) have the interest and potential expertise to perform invasive endovascular procedures. Since no common pathway existed to achieve competency in the performance of catheter-based vascular interventions, there was a compelling need for the minimum requirements to conform to a uniform standard. This document established recommendations for formal training requirements and alternative routes to achieving competence in peripheral catheter-based interventions. Similar guidelines for competency/credentialing of practitioners to perform endovascular stent grafting of the thoracic aorta²⁹ and carotid stenting³⁰ provide recommendations regarding physician training and credentialing to facilitate the safe and orderly dissemination of these endovascular therapies into clinical practice.

Since no published consensus guidelines exist for catheter-based hemorrhage control, it is important to partner with vascular surgery and IR colleagues who are currently credentialed in these lifesaving techniques to gain experience with catheter-based hemorrhage control. To facilitate a safe application of REBOA and other catheter-based hemorrhage endovascular techniques, we propose the following:

1. Determine fundamental components to obtain competency in catheter-based hemorrhage control:

- a. Define minimum education, training, experience, as well as cognitive and technical skills necessary for the performance of catheter-based peripheral vascular procedures.
- b. Define specific procedures (REBOA, angiography, angiographic embolization) and patient population that these procedures pertain to (emergent vs. elective).
2. Develop a statement on clinical competence to assist in the assessment of physicians' expertise in the performance of catheter-based hemorrhage control.
3. Whenever possible, the specifications must be based on published data that link these factors with competence or, in the absence of such data, on the consensus of expert opinion.
4. Consider common practice settings for catheter-based hemorrhage control and attempt to accommodate a number of ways in which physicians can substantiate expertise and competence in these catheter-based vascular procedures.

An additional strategy to consider is to hire a faculty member from the growing group of acute care surgeons who have completed a standard vascular surgery fellowship in addition to a trauma, surgical critical care, and/or acute care surgery fellowship. They can serve as expert faculty and provide training for other faculty members. There is no question that acute care surgeons must commit to the documentation of initial competence and maintenance of competency in endovascular procedures for catheter-based hemorrhage control to promote safe application of these procedures for our trauma patients.

REMAINING QUESTIONS

Regarding catheter-based hemorrhage control, several issues remain as barriers to adoption among acute care surgeons. Research is required to develop rapidly deployable, less invasive endovascular methods to monitor hemodynamics, stabilize vascular disruption within the torso, control hemorrhage, sustain central myocardial and cerebral perfusion, and subsequently reduce mortality. Specific devices and methods should also be developed and improved to manage vascular disruption and hemorrhage from the junctional regions between the torso and the extremities. New devices and methods should address balloon placement in medical environments where fluoroscopic guidance is not available such as forward military settings and non-Level 1 trauma centers.³¹ Finally, there are questions such as who should perform these endovascular interventions—trauma or vascular surgeons? If trauma surgeons will use these new techniques, what is the optimal training and credentialing for them? Should there be joint or separate credentialing boards? Can (or should?) these approaches be expanded to nonsurgeons? Should these techniques and capabilities be extended outside Level 1 trauma centers, and if so, what physician specialties would benefit from additional endovascular training?

Regarding the use of hybrid ORs for hemorrhaging trauma patients, the major remaining question is to determine the needs of individual patients and hospitals. For some hospitals, a hybrid OR may already be available for another specialty such as cardiovascular or neurosurgery, and it may be possible to use these preexisting facilities. If a hybrid OR is not already available, is it financially feasible to build one from the ground up and is the trauma patient volume large

enough to financially support a dedicated THOR, or will another specialty, such as IR, help share the cost of building a hybrid OR? If no funding is available, can hospitals minimize patient movement or improve rapid access to catheter-based hemorrhage control in other ways? Once the decision has been made to build a dedicated THOR, what is the optimal design, and what equipment should be included? What are the specific tradeoffs of using a more traditional OR table in conjunction with C-arm fluoroscopy that is better for surgery but potentially worse for imaging? What are the staffing needs for a THOR, and can the THOR be used during regular business hours on other procedures to keep skills fresh and use the room, staff, and equipment more efficiently? Fundamentally, is the THOR conceived primarily as an imaging theater that permits occasional surgery or as a resuscitative OR that facilitates imaging and image-guided endovascular procedures? Can it be a blend of both and still function? Finally and most importantly, will a THOR or RAPTOR improve traumatic hemorrhage patient outcomes? Obviously, there are many different solutions individual hospitals may devise to improve the care of hemorrhaging trauma patients, and no one solution will be perfect for every institution.

As methodologies and algorithms for aortic occlusion after trauma continue to evolve, it is also paramount that effective means be established to study their use and capture outcomes. To date, the majority of data on the clinical use of traditional aortic occlusion modalities (via either thoracotomy or laparotomy) have been retrospective and limited in nature. The largest collated description of these experiences³² was a landmark study but is now more than a decade old and was limited by the absence of consistent definitions and the variability of used practices between published series. No large multicenter prospective study of the clinical use of aortic occlusion in trauma has previously been conducted. To capture this information among changing practices, those present at the THOR meeting developed and implemented the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study.³³ This study, developed through the support of the American Association for the Surgery of Trauma, is designed to prospectively capture experiences with aortic occlusion of all types in a multicenter trauma setting. It is our hope that such important data will assist recording outcomes in the face of emerging technologies and help to refine treatment algorithms.

CURRENT RECOMMENDATIONS

During the February 2013 meeting, all these possibilities were discussed in detail. Although the group did not advocate a single plan for every hospital, we did agree on a few key recommendations for the treatment of hemorrhaging trauma patients overall,

1. Teach ultrasound-guided percutaneous vascular access to all acute care physicians.
2. Use REBOA in the ED in appropriate patients after appropriate physician training.
3. Minimize transfers and treatment delays by bringing hemorrhage control capabilities to the patient,

4. Admit critically trauma ill patients with hemorrhage directly to a hybrid OR when possible.
5. Make sophisticated imaging and monitoring immediately available in all patient locations.
6. Combine minimally and maximally invasive capabilities in one OR suite when possible.
7. Provide consistent resuscitation and temperature control capabilities regardless of location.
8. Create new multimodal interventions, including methods of REBOA that do not require fluoroscopic guidance that could be used outside a Level 1 trauma center.
9. Define standardized competency, and develop credentialing for endovascular procedures performed by nonvascular surgeons.
10. Develop methodologies to track outcomes of changing patterns in aortic occlusion for trauma.

SUMMARY

Given how rapidly this area of surgical care is changing, these recommendations may be dated soon after they are published and will likely require frequent updating. The challenge we currently face is learning from the implementation of previous paradigm changes and driving these new trauma techniques in a data-driven, economically sound fashion, focused on quality outcomes for the patient. This will require high-quality research and a productive interaction between academia, academic surgical and medical societies as well as industry.

AUTHORSHIP

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DISCLOSURE

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